

## **EXHIBIT M**

UNITED STATES BANKRUPTCY COURT  
DISTRICT OF MASSACHUSETTS  
EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING  
PHARMACY, INC.,

Debtor.

Chapter 11

Case No. 12-19882-HJB

**PLAINTIFFS' STEERING COMMITTEE'S DECLARATION IN SUPPORT OF  
APPROVAL OF THE FIRST AMENDED JOINT CHAPTER 11 PLAN**

The undersigned, members of the Plaintiffs' Steering Committee ("PSC") appointed by the Court in this associated MDL, *In Re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 1:13-md-2419 ("MDL"), provide the Court with this declaration in support of the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (the "Plan"). The undersigned declare and state as follows:

**THE OUTBREAK**

1. In September 2012, initial reports from the Tennessee Board of Health to the national Centers for Disease Control and Prevention ("CDC") indicated a link between fungal meningitis cases in that state and products compounded by the New England Compounding Center ("NECC") in Framingham, Massachusetts. State and federal authorities including the CDC, Food and Drug Administration ("FDA"), Federal Bureau of Investigation ("FBI"), Drug Enforcement Administration ("DEA"), United States Attorney for Massachusetts ("U.S. Attorney for MA"), and Massachusetts Board of Pharmacy ("MA Board") began an investigation.

2. On October 3, 2012, NECC surrendered its pharmacy license. It ceased all production and initiated recall of all drug products prepared for injections in and around the spinal cord (known as intrathecal administration).

3. Soon after, numerous civil actions were filed in state and federal courts across the country alleging a variety of claims, including personal injury, wrongful death, and consumer protection claims. These suits were brought against three categories of defendants: (1) NECC's principals, directors, and affiliated companies ("Affiliated Defendants"); (2) vendor companies that provided services to NECC ("National Defendants"); and (3) healthcare clinics and facilities, doctors, and staff involved in the purchase and administration of contaminated products from NECC to patients in numerous states ("Clinic Related Defendants").

4. According to the CDC, the three contaminated lots of methylprednisolone acetate compounded at NECC were distributed to 76 separate healthcare facilities across 23 states. As of its last case update on October 23, 2013, the CDC identified more than 64 deaths and 751 cases of confirmed fungal meningitis or other paraspinal infection associated with NECC's contaminated products.

## **FORMATION OF THE MDL AND INITIAL BANKRUPTCY PROCEEDINGS**

5. As early as November 2, 2012, cases against NECC were filed in federal and state courts in Massachusetts and across the country (e.g., *Erkan v. New England Compounding Pharmacy, Inc.*, 12-cv-12052-FDS (D. Mass.)).

6. On December 21, 2012, NECC filed its petition for bankruptcy.<sup>1</sup>

7. On February 12, 2013, the Judicial Panel on Multidistrict Litigation consolidated all related federal actions nationwide in the United States District Court for the District of Massachusetts.<sup>2</sup>

8. By Order dated May 31, 2013, the MDL Court asserted "related-to" jurisdiction over all actions against NECC and its affiliated entities and individuals pending or in the process

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<sup>1</sup> Dkt. 1.

<sup>2</sup> JPML (MDL No. 2419) Dkt. 119.

of removal to federal court and all cases against NECC and its affiliated entities and individuals pending in state courts across the country.<sup>3</sup>

9. After the MDL was created, the MDL Court sought input from plaintiffs' counsel on the creation of a structure for leadership of plaintiffs in the MDL.<sup>4</sup> The Court received submissions from various plaintiffs' attorneys and groups of attorneys seeking leadership positions. On April 9, 2013, the Court appointed Thomas M. Sobol of Hagens Berman Sobol Shapiro LLP as Lead Counsel. The Court also appointed a seven person PSC and a Federal-State Liaison.<sup>5</sup>

10. Among other responsibilities, the Court appointed Lead Counsel to chair the PSC, present the position of plaintiffs in all pretrial proceedings, delegate tasks to other plaintiffs' counsel to "ensure that pretrial preparation for the plaintiffs is conducted effectively, efficiently, and economically,"<sup>6</sup> and to "coordinate and lead discussions with the Court, plaintiffs' counsel and other stakeholders (for example, the Chapter 11 Trustee and its counsel, the Creditors' Committee and its counsel, other defense counsel, and non-parties) to ensure that . . . unnecessary expenditures of time and funds are avoided, and any negotiations are reasonably efficient and productive."<sup>7</sup> Pursuant<sup>8</sup> to the Court's order, Lead Counsel is involved in all settlement discussions "whether taking place in the MDL or the bankruptcy."<sup>8</sup>

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<sup>3</sup> MDL Dkt. 170.

<sup>4</sup> See unnumbered MDL Dkt. entry of March 12, 2013.

<sup>5</sup> The members of the PSC include (i) Thomas M. Sobol of Hagens Berman Sobol Shapiro, LLP, (ii) Mark Chalos of Lieff Cabraser Heimann & Bernstein, LLP, (iii) Kim Dougherty of Janet Jenner & Suggs, LLC, (iv) Marc Lipton from Lipton Law, (v) Patrick Fennell of Crandall & Katt, (vi) J. Gerard Stranch, IV of Branstetter, Stranch & Jennings PLLC, and (vi) Mark Zamora of the Zamora Firm.

<sup>6</sup> Order Appointing Lead Counsel and Plaintiffs' Steering Committee, MDL Dkt. 82 at 3.

<sup>7</sup> *Id* at 4.

<sup>8</sup> *Id.*

11. The PSC members' responsibilities include, in relevant part, to "negotiate and propose settlement of cases on behalf of plaintiffs or plaintiffs groups, including . . . pursuing all settlement options concerning any claim or portion thereof of any case filed in this litigation."<sup>9</sup>

### **PSC MEMBERS' EXPERIENCE**

12. As seasoned and accomplished plaintiffs' attorneys, each of the members of the PSC routinely handle matters against large corporations in both distressed and non-distressed situations. Each has litigated, and many tried, cases in state and federal courts across the country in pharmaceutical related cases involving personal injury as well as mass torts – some on behalf of individual clients and others in multi-party, large-scale complex class actions. Many of the members of the PSC have tried cases involving bankruptcy and complex financial matters.

13. Members of the PSC have been involved in this litigation from its inception in the wake of the fungal meningitis outbreak in the fall of 2012. PSC members filed the first cases in federal court in this district in early November 2012. Also in November 2012, PSC members sought and obtained an attachment on the physical property of NECC in the amount of \$5 million. In December 2012, PSC members were instrumental in seeking and conducting the early inspection of the NECC facility. The inspection uncovered information about new potential defendants, including Liberty (company who built the cleanroom), Victory (the HVAC contractor), and UniFirst (company who cleaned NECC and its cleanrooms).

### **THE COURT ORDERED MEDIATION PROGRAM**

14. In June and July 2013, in conjunction with the Chapter 11 Trustee ("Trustee") and the Official Committee of Unsecured Creditors ("OCC"), subpoenas were served on all clinics identified by the CDC as having received one of the three contaminated lots of

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<sup>9</sup> *Id.* at 7.

methylprednisolone acetate (“MPA”) compounded by NECC. The goal of the subpoenas was to procure a comprehensive list of all patients exposed to the contaminated products.

15. By Order dated August 15, 2013, the MDL Court endorsed a mediation program to facilitate and encourage the settlement of tort claims with those defendants willing to participate. Over the ensuing 18 months, multiple mediations were undertaken with the Affiliated Defendants, the National Defendants and some Clinic Related Defendants, resulting in the settlements incorporated in the proposed Plan (the “Settlements”).<sup>10</sup> Some mediations were undertaken as part of the court-supervised mediation program; some were done privately. In the private Insight mediation, both MDL Judges, Judge Zobel and Judge Boal, spent a full day with the parties and two private mediators in an effort to finalize the mediation.

### **THE SETTLEMENTS**

16. The Proposed Chapter 11 Plan create a Tort Trust for the benefit of tort claimants. The Tort Trust will be funded by Settlements with National Defendants as follows with estimated amounts (subject to fees and expenses):

<b>National Settling Defendant</b>	<b>Expected Contribution</b>
NECC Owners/Shareholder Settlement	\$47,750,000 – 75,000,000
PMIC/Maxum Settlement	\$25,200,000
Ameridose Settlement	\$10,000,000
GDC Settlement	\$3,750,000
ARL Settlement	\$6,400,000
Victory Settlement	\$5,500,000
UniFirst Settlement	\$30,500,000
Liberty Settlement <sup>11</sup>	\$1,000,000
<b>Total Estimated Amount:</b>	<b>\$130,100,000 - \$157,350,00</b>

<sup>10</sup> Order on Mediation Program, MDL Dkt. 394.

<sup>11</sup> The Liberty Settlement had not been finalized when the Trustee filed the Plan Supplement, and was the subject of a 9001 Motion filed on April 20, 2015 (Dkt. 1219).

17. In addition to the settlements with National Defendants, the Chapter 11 Trustee has entered into the following settlements with certain Clinic Related Defendants (subject to fees and expenses):

Provider Defendant	Contribution
High Point Settlement	\$3,500,000
Inspira Settlement	\$16,000,000
Insight Settlement	\$40,000,000
<b>Total Amount:</b>	<b>\$59,500,000</b>

### **WORK INVOLVED IN SECURING THE SETTLEMENTS**

18. The interests of tort victims have been vigorously pursued by competent and qualified counsel. The Settlements are the product of nearly two and a half years of substantial work and oversight undertaken by the PSC and its appointed state chairs, the Trustee, the OCC, and the PSC's designated attorneys.

19. Given the limited money and resources of NECC, Affiliated, National and Clinic Related Defendants, it was clear from the beginning of the litigation that tort claimants would be challenged to receive fair compensation for their injuries. Extensive and protracted litigation of claims would serve only to further deplete the resources available to compensate victims and postpone for years the ability of victims or their families to receive much deserved compensation.

### **REASONABLENESS OF THE SETTLEMENTS**

20. The undersigned members of the PSC believe that the proposed settlements are reasonable for the following reasons:

**A. Difficulties faced in the MDL Litigation.**

21. This case consists of a complex framework of interrelated claims and parties subject to federal and state tort, contract, consumer protection, contribution and indemnity laws

and the United States Bankruptcy Code. The sheer number of injured and affected victims ranges in the thousands and the cases comprise dozens of defendants in the aggregate.

22. The number of defendants involved in the MDL presented challenges. At its peak, the MDL involved dozens of defendants including NECC, the individual insiders, NECC affiliated companies, NECC's vendors (clean room installers, testing companies, and cleaners), dozens of pain clinics, and doctors. The proposed Plan resolves claims against all Affiliated and National Defendants and some Clinic Related Defendants and considerably narrows the pool of defendants against whom the PSC must actively litigate.

23. In the absence of the settlements, the number of defendants and complexity of the litigation would likely postpone the time of trials of tort claims in the MDL.

**B. Establishing liability against settling defendants at trial would be difficult and costly and take years of continued litigation.**

24. With the exception of NECC, all of the participating entities and individuals vigorously disputed liability, as described in more detail in the declarations addressing settlement with each contributing entity. While the PSC was prepared to litigate against each and every defendant, overcoming their asserted defenses would be a challenge with respect to most defendants and would require significant expenditure of resources over a long period of time. The outcome of such litigation would also be uncertain, leaving victims waiting years for compensation that might never occur.

**C. Tort victims support the Plan.**

25. Collectively, the undersigned represent hundreds of victims of the NECC tragedy. Our clients have been fully apprised of the details of the Settlements and the proposed Plan, both through notices issued by order of this Court and through our regular client updates and communications. Our clients are overwhelmingly in favor of the Settlements and approval of the proposed Plan.

**D. Specific settlements are reasonable.**

**1. NECC, insiders, affiliated entities, and their insurers**

26. The insiders, Affiliated Defendants, and their insurers took the position that they needed non-debtor releases to discharge their claims against the debtor. These non-debtors did not want to settle only NECC claims, they also wanted to resolve victims' claims against them and took the position that a non-debtor release was necessary to extinguish those claims. The Trustee, with the PSC and the OCC's support and consent, was willing to give them non-debtor releases in exchange for the wholesale resolution of victims' claims.

27. After diligent review of available information and resources, the PSC believes that the contributions made by individual insiders meet or exceed the amounts that the PSC could reasonably expect to have recovered through litigation.

28. As to the contributions made by the insurers for NECC, Ameridose, and the insiders, the PSC believes that those contributions fairly reflect a reasonable compromise in light of various exclusions and other defenses, and may exceed the amounts of coverage that could be obtained through litigation.

29. For these and other reasons, the PSC believes that the proposed settlement with NECC, the insiders, the affiliated defendants, and their insurers is fair and reasonable and in the best interest of all tort victims in the MDL.

**2. National Defendant settlements**

**a. UniFirst settlement**

30. NECC hired Unifirst to clean the NECC facility, including the cleanrooms where the contaminated MPA was compounded.

31. The prospects of proving liability against UniFirst in litigation were uncertain at best. While the PSC believed it could prove UniFirst's negligence, the PSC harbored serious

reservations about whether it could prove that UniFirst's negligence was a proximate cause of victim's injuries. The correlation between UniFirst's visits and bacterial and/or fungal contamination in the NECC cleanrooms was unclear at this stage of the litigation. It was also unclear, despite UniFirst's contractual obligations, that NECC could have reasonably expected UniFirst to adequately sanitize the cleanroom when UniFirst only visited the NECC facility for 90-120 minutes once a month.

32. In light of these and other disputed issues, the PSC believes that the \$30.5 million proposed settlement with UniFirst is fair and reasonable and in the best interest of all tort victims in the MDL.

**b. ARL settlement**

33. ARL tested the sterility of NECC-compounded products, including the contaminated MPA.

34. ARL and its insurer disputed that the PSC could ever prove that ARL tested any final product from any of the three contaminated lots of MPA, that any testing conducted by ARL yielded an inaccurate result, or that any act or omission by ARL caused damage to any individual claimant. As the samples of MPA sent to ARL for sterility testing were apparently not taken from the final product after the fill procedure; it is possible that the vials tested were, in fact, sterile and the contaminated vials of MPA distributed to clinics and hospitals were contaminated during the fill procedure. Even if the PSC could prove ARL's negligence, it was unclear that the PSC could show that ARL's negligence was a proximate cause of the injuries suffered by any of the personal injury claimants.

35. ARL and its insurer took the position that there was, at most, only \$3 million in insurance coverage (which would be reduced by defense costs). The settlement includes a \$6.4 million contribution by ARL and its insurers.

36. Given these and other disputes, the PSC believes that the proposed settlement with ARL is fair and reasonable and in the best interest of all tort victims in the MDL.

**c. Victory settlement**

37. Victory installed and maintained NECC's HVAC system, including the HVAC system in the cleanrooms.

38. Victory contested that the PSC would never be able to prove that Victory negligently designed or installed NECC's HVAC system, asserting that Victory did not design the location of the air intake (pulling from an adjacent recycling facility), install, and/or maintain the fan filter boxes or HEPA filters in the clean room ceiling (where openings were found that would permit contaminants to enter the cleanroom). Victory also maintained that it did not have an ongoing responsibility to service the HVAC system.

39. The PSC's expert found *exserohilum rostratum* and *aspergillus fumigatus* inside the HVAC system, but the impact of this finding on Victory's liability was unclear. The PSC maintained that it showed Victory's liability. Victory maintained that it showed the HVAC system worked properly and kept contaminants *out* of the cleanroom. Even if the PSC could prove Victory's negligence, it is unclear that the PSC could show that Victory's negligence was a proximate cause of the tort claimants' injuries.

40. The PSC and Victory disputed whether Victory's insurance coverage in fact totaled \$7 million for the relevant time period. The settlement includes a \$5.5 million contribution.

41. Given these and other disputes, the PSC believes that the proposed settlement with Victory is fair and reasonable and in the best interest of all tort victims in the MDL.

**d. Liberty settlement**

42. Liberty designed and built the cleanrooms.

43. Liberty filed a motion for summary judgment in the MDL that argued, *inter alia*, that Liberty bore no responsibility because (i) NECC made significant modifications to the Liberty built cleanrooms after construction, (ii) Liberty did not owe the victims a duty, and (iii) Liberty's design failures did not proximately cause victims' injuries. The PSC opposed Liberty's motion for summary judgment, but, as Judge Zobel observed in her order denying Liberty's motion, “[T]he question is a close one” and there are “serious questions as to the ability of plaintiffs to prove causation at trial.”<sup>12</sup>

44. Liberty's gross annual revenue is in the low seven figures. Liberty has no significant tangible assets. Liberty's insurance coverage is the subject of a Declaratory Judgment Action. In that action, Liberty's insurer claimed that it was not obligated to cover any injuries suffered by victims because of an “organic pathogen exclusion” written into the policy.

45. The proposed settlement with Liberty includes a \$450,000 payment by Liberty, and a \$550,000 contribution by its insurers.

46. For these and other reasons, the PSC believes that the proposed settlement with Liberty is fair and reasonable and in the best interest of all tort victims in the MDL.

### **3. Clinic-related defendants' settlements**

#### **a. Insight settlement**

47. The Insight clinic is located in Roanoke, VA. Approximately 153 plaintiffs sued Insight as a result of injuries and deaths caused by having received one or more injections of contaminated MPA administered at Insight's Roanoke clinic.

48. The Insight mediation resulted in a Settlement and Release Agreement between the represented Virginia claimants and Virginia defendants (including Insight and individual

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<sup>12</sup> 13-md-2419 (Dkt. 1613).

doctors), pursuant to which the Virginia defendants will pay \$40 million to the estate, primarily for the benefit of the tort claimants who were injected at Insight.

49. Insight and the doctors asserted cross claims based on contractual indemnity. The doctors claimed that purchasing medication was Insight's sole responsibility; Insight claimed that the choice of medication was solely the doctor's decision. During the mediation, it became clear that victims could not settle with Insight without simultaneously settling with the doctors (or vice versa).

50. Both Insight and the doctors contested liability and presented arguments that previewed what would have been their vigorous defense. The PSC was particularly concerned about whether – even in the face of contrary law and evidence – the doctors could convince juries that Insight and/or NECC were the true bad actor and that therefore the doctors should not be found liable.

51. The Virginia defendants disputed the total amount of insurance coverage available. The PSC grappled with the reality that once the primary Insight policy was exhausted, the secondary policy was a wasting policy that paid defense costs out of the policy coverage limits of only \$10 million. The \$40 million sum consists, in part, of a contribution by Insight and its insurers alone of \$38.5 million, which is \$7 million in excess of its stated available insurance coverage.

52. For these and other reasons, the PSC believes that the proposed settlement with the Virginia defendants (including Insight) is fair and reasonable and in the best interest of tort victims in the MDL.

**b. High Point settlement**

53. High Point is a North Carolina health care provider that purchased and administered NECC's products to its patients, including contaminated MPA lots that were

compounded by NECC during 2012. Approximately 22 tort claimants filed proof of claim in the bankruptcy stemming from injections received at High Point.

54. High Point and its insurers strongly contested that the PSC would be able to prove that High Point breached the standard of care owed to its patients, nor that any potential breach proximately caused injuries to the claimants. The PSC recognized that (i) approximately 95% of the medical malpractice cases tried in North Carolina end in verdicts for the defendant and (ii) the North Carolina medical malpractice non-economic damages cap of \$500,000 also informed the PSC's thinking.

55. For these and other reasons, the PSC believes that the \$3.5 million proposed settlement with High Point is fair and reasonable and in the best interest of all tort victims in the MDL.

**c. Inspira settlement**

56. At the time the contaminated MPA was administered in 2012 Inspira Health Network, Inc. was known as "South Jersey Health System, Inc.," and its medical facilities in Vineland and Elmer, New Jersey, were owned and operated by a subsidiary named: "South Jersey Hospital, Inc." South Jersey Health System in 2013 became a part of the "Inspira Health Network" in connection with a consolidation of southern New Jersey community hospitals.

57. Inspira maintained that it acted reasonably and within applicable standards of care, did not know of NECC's shortcomings and indeed viewed itself a victim of NECC and the NECC insider's conduct. The PSC believed that it could rebut Inspira's position and prove Inspira's negligence, but recognized difficulty in recovering meaningful amounts for victims in light of causation issues and New Jersey allocation of fault law. Under New Jersey law, to hold Inspira jointly and severally liable for any tort victim's entire judgment, that victim would need to establish that Inspira was at least sixty percent (60%) at fault. While the PSC believed

claimants would likely prevail on the question of Inspira's relative fault, the reality of NJ state comparative fault law had to be seriously considered and factored in to valuing the claims.

58. The Inspira settlement of \$16 million is a substantial portion of Inspira's entire available insurance coverage.

59. For these and other reasons, the PSC believes that the proposed settlement with Inspira is fair and reasonable and in the best interest of all tort victims in the MDL.

### CONCLUSION

60. It is the belief of the undersigned members of the PSC that the Settlements are fair, reasonable, equitable, and serve the best interests of tort victims in the MDL and that the Plan should be approved.

The undersigned declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

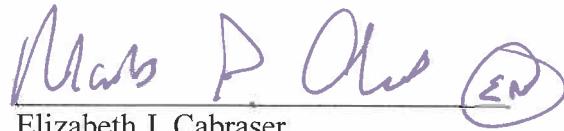
Dated: April 27, 2015

Respectfully submitted,



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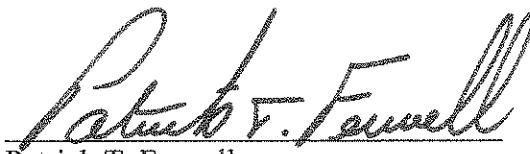
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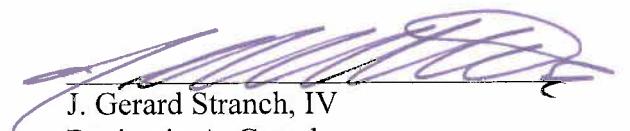
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